IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: TOVEY=1A

In re Application of:	)	Conf. No.: 1869
	)	
Michael TOVEY	)	Art Unit: 1614
	)	
Appln. No.: 09/243,030	)	Examiner: R. Cook
	)	
Filed: February 3, 1999	)	Washington, D.C.
	)	
For: THERAPEUTIC APPLICATIONS OF HIGH DOSE ...	)	May 8, 2006
	)	

RESPONSE

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendments
401 Dulany Street
Alexandria, VA 22314

Sir:

The present communication is responsive to the official action of January 6, 2006. Claims 22-57 presently appear in this case. No claims have been allowed. The official action of January 6, 2006, has been carefully studied. Reconsideration and allowance are respectfully urged.

Briefly, the present invention relates to a method for treating a viral infection by the administration of interferon via oromucosal contact. The dose is a high dose which is greater than 20 x 10^6 IU of interferon for a 70 kg human, preferably greater than 30 x 10^6 IU of interferon, which

dose is in excess of a dose of the same interferon which induces a pathological response when parenterally administered.

Claims 22-57 have been rejected on the ground of non-statutory obviousness-type double-patenting as being unpatentable over claims 1-19 of U.S. patent 6,361,769. The examiner states that the claims are not patentably distinct from each other because the method of stimulating host defense mechanisms comprising administering interferon via oromucosal contact of '769 includes treating a viral infection recited in the instant application. The examiner states that a timely filed terminal disclaimer may be used to overcome an actual or provisional rejection based on a non-statutory double-patenting ground.

While applicant does not concede that the present claims are patentably indistinct from the claims of the '769 patent, nevertheless, in order to obviate this rejection, a terminal disclaimer is being filed herewith. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

Claims 22-32, 36-52, 56 and 57 have been rejected on the ground of the non-statutory obviousness-type double-patenting as being unpatentable over claims 1 and 3-15 of U.S. patent 6,207,145 and claims 1-14 and 16 of U.S. patent 5,997,858. The examiner states that the claims are not

patentably distinct from each other as the method for treating a neoplastic condition by administering interferon by oromucosal contact of '760 and '858 render the instant method obvious when the method is used to treat a neoplastic condition caused by a virus. This rejection is respectfully traversed.

All of the present claims are directed to a method for treating a viral infection. The claims of the '145 and '858 patents are directed only to the treatment of a neoplastic condition. One of ordinary skill in the art, aware that a particular medicament may be efficacious for the treatment of a neoplastic condition, would not consider it *prima facie* obvious that such a medication would be useful for the treatment of a viral infection. The fact that some neoplastic conditions may have originally been caused by a virus does not make it obvious that a medicament that will treat the neoplastic condition will necessarily treat that virus (or any other virus) or that the treatment of that virus might have any effect on the neoplastic condition that was caused thereby. These are separate and distinct conditions. Despite the fact that a neoplastic condition might be caused by a virus, it would not be obvious to treat any viral condition with an anti-neoplastic agent and have a reasonable expectation of success in treating that viral infection. In the absence of secondary prior art showing the obviousness of

using anti-neoplastic medications for treatment of viral infections, this obviousness-type double-patenting rejection is inappropriate. Reconsideration and withdrawal thereof are respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are hereby earnestly solicited.

Respectfully submitted,

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